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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/990,960
Filing Date	11/21/2001
First Named Inventor	Jeffrey A. Hall
Art Unit	3739
Examiner Name	Peter J. Vrettakos
Total Number of Pages in This Submission: 10	Attorney Docket Number: 55405

ENCLOSURES *(check all that apply)*

- ☐ Fee Transmittal Form
- ☐ Fee Attached
- ☐ Amendment / Reply
- ☐ After Final
- ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
- ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
- ☐ After Allowance communication to Technology Center (TC)
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below)*:
  1. **Request for Certificate of Correction**
  2. **Form PTO 1050**
  3. **Postcard**

Remarks

Re: USPNo.: 6,796,980 B2

Customer No.: 24201

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	**FULWIDER PATTON LEE & UTECHT, LLP** **Thomas A. Runk, Reg. No. 30,679**
Signature	Thomas A. Runk
Date	**April 4, 2005**

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria,VA 22313-1450 on the date shown below:

Typed or printed name	**Thomas A. Runk**		
Signature	Thomas A. Runk	Date	**April 4, 2005**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Inventor: Jeffrey A. Hall

Patent No.: 6,796,980 B2

Serial No.: 09/990,960

Issued: September 28, 2004

Filed: November 21, 2001

For: SYSTEM AND METHOD FOR VALIDATING AND TROUBLESHOOTING ABLATION SYSTEM SET-UP

Examiner: Peter J. Vrettakos

Group Art Unit: 3739

Docket No.: HRT-55405

REQUEST FOR CERTIFICATE OF CORRECTION

Certificate of Corrections Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The above-identified patent has been found to have the errors set forth in the enclosed Certificate of Correction. It is requested that this Certificate of Correction be issued and returned to us. Since the errors occurred in the final printing phase of the patent, no fee is enclosed. However, should the Office determine that a fee is required, please charge our account no. 06-2425.

The errors are verifiable in the patent application file as follows:

ERROR	VERIFICATION
Column 4, line 47, delete "possible" and insert --Possible--.	See page 6, line 8 of Specification.
Column 7, line 54, delete "preferably" and insert --Preferably--.	See page 10, line 19 of Specification.
Column 10, line 11, delete "prompts" and insert --Prompts--.	See page 13, line 28 of Specification.
Column 11, line 53, delete "prompts" and insert --Prompts--.	See page 16, line 3 of Specification.
Column 12, line 40, delete "or" and insert --of--.	See Amendment dated June 7, 2004.
Column 12, line 47, delete "staring" and insert --starting--.	See Amendment dated June 7, 2004.

A duplicate of this document is attached.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By: Thomas A. Runk

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Registration No. 30,679

TAR/pp
Enclosures

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(Also Form PTO 1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,796,980 B2

DATED : September 28, 2004

INVENTOR(S) : **Jeffrey A. Hall**

It is certified that errors appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 4, line 47, delete "possible" and insert --Possible--.
Column 7, line 54, delete "preferably" and insert --Preferably--.
Column 10, line 11, delete "prompts" and insert --Prompts--.
Column 11, line 53, delete "prompts" and insert --Prompts--.
Column 12, line 40, delete "or" and insert --of--.
Column 12, line 47, delete "staring" and insert --starting--.

81796.1

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PATENT NO. 6,796,980 B2

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shaft 24. The electrode system 28 may include a tip electrode 42. (For clarity of illustration, only six band electrodes 40 are shown in FIG. 2 and only four band electrodes 40 are shown in FIG. 3 although as stated, a preferred embodiment may include many more.) The band electrodes 40 are arranged so that there is an electrically non-conductive space 44 between adjacent electrodes. In one configuration of the electrode system 28, the width of the band electrodes 40 is 3 mm and the space 44 between the electrodes is 4 mm. The total length of the electrode system 28, as such, is approximately 8 cm.

The band electrodes 40 are formed of a material having a significantly higher thermal conductivity than that of the biological tissue to be ablated. Possible materials include silver, gold, chromium, aluminum, molybdenum, tungsten, nickel, platinum, and platinum/10% iridium. Because of the difference in thermal conductivity between the band electrodes 40 and the tissue, the electrodes cool off more rapidly in the flowing fluids at the biological site. The band electrodes 40 are sized so that the surface area available for contact with fluid in the heart, *e.g.*, blood, is sufficient to allow for efficient heat dissipation from the electrodes to the surrounding blood. In a preferred embodiment, the band electrodes 40 are 7 French (2.3 mm in diameter) with a length of 3 mm and a thickness in the range of about .002 mm to about .010 mm.

Associated with the electrode system 28 are thermal sensors 46 for monitoring the temperature of the electrode system 28 at various points along its length. In one embodiment, each electrode 40, 42 has a thermal sensor 46 mounted to it. In another embodiment of the electrode system 28 a thermal sensor 46 is mounted on every other band electrode 40. Thus for a catheter having twelve electrodes, there are thermal sensors on six electrodes. In yet another embodiment of the electrode system 28 the odd numbered electrodes have one thermal sensor 46 while the even numbered electrodes have two thermal sensors. In yet another embodiment of the electrode system 28 the electrodes have two thermal sensors 46. In FIG. 3, which shows an embodiment having one thermal sensor for each electrode, there is shown a single power lead 48 for each electrode 40 to provide power to each electrode for ablation purposes and two temperature leads 50 for each thermal sensor 46 to establish a thermocouple effect. In another configuration (not shown), the power lead acts as one of the thermocouple leads thereby reducing the number of wires. Details of such configurations are disclosed in U.S. Patent Nos. 6,042,580, 6,045,550 and 6,049,737 the disclosures of which are hereby incorporated by reference. In alternate embodiments, the thermal sensors 46 may include

disconnect and check cable connector and patient-return-electrode receptacle pins", "reconnect cable".

If only the power control system display 84 is available, a patient-return-electrode/connection troubleshooting subroutine stored within the processor/controller 34 is invoked and similar type messages are displayed in accordance with the capabilities of the display 84. In another embodiment a green LED (not shown) on the power control system above the patient-return-electrode receptacle 66 instantly verifies proper cable connection. Once the corrective actions are completed, the user notifies the patient return electrode-connection troubleshooting routine through a user interface, *e.g.*, front panel control on power control system or computer keyboard. The set-up algorithm is reinvoked and operation returns to step S1 to verify patient return electrode connection. Steps S1, S2 and S3 are repeated as necessary depending on the number of patient return electrodes 18.

At step S4, the set-up algorithm verifies adequate contact between the patient return electrode pad and the biological site 12. With reference to FIG. 4, the set-up algorithm does this by obtaining a measurement of the impedance between the two return pads 60, 62 and comparing the impedance to an expected value. The impedance measurement is obtained passively through circuitry within the processor/controller 34 which interfaces with the patient return electrode 18 through the patient-return-electrode monitoring lines 32 and the patient return electrode connection previously verified in step S1. Preferably, the patient return electrode pad is secured to the biological site 12 such that the entire surface area of the two return pads 60, 62 is in contact with the site. The expected impedance value is within the range of approximately 80 ohms and 120 ohms. A measured impedance value greater than the expected value is indicative of inadequate contact. In another embodiment, the processor/controller 34 repeatedly samples the impedance value and monitors the samples for a high standard deviation, indicative of inadequate contact. This is based on the recognition that the impedances measured across a secure patient return electrode are substantially consistent, *i.e.*, they do not deviate significantly from an average value, while impedances measured across a loose patient return electrode are inconsistent due to periodic and repeated patient movement relative to the return electrode, such as that caused by patient breathing, and accordingly have a high standard deviation.

At step S5, if the measured impedance is less than the expected impedance or the standard deviation is indicative of adequate contact, contact is confirmed and the set-up

to communicate, check for correct baud rate and correct serial data port", "unable to find serial data port, confirm correct active serial port in computer setup."

If only the power control system display 84 is available, a communication troubleshooting subroutine stored within the processor/controller 34 is invoked and similar type messages are displayed on the display 84. Once the corrective actions are completed, the user notifies the troubleshooting routine through a user interface. The set-up algorithm is reinvoked and operation returns to step S10 to confirm communication between the processor/controller 34 and the computer 30.

At step S13 the set-up algorithm verifies EP monitoring system connection by sequentially outputting a pulse signal to each pin of the EP-monitoring-system receptacle 86 (FIG. 1) on the power control system 16. For a multiple channel ablation system, the pulses are output in sequence starting from the channel 1 pin, with a slight time delay between pulses, such as one second. If the lead 88 (FIG. 5) connections between the EP interface 68 and EP recorder 70 is correct, the pulses are displayed on the EP recorder 70 as a progressive sequence starting from channel 1 and ending with the last channel. In one embodiment, the sequence of pulse signals repeats until correct connection is confirmed by the user. This allows the user to reconnect leads 88 as necessary until proper connection is achieved. In another embodiment, the sequence of pulses repeat a set number of times and may be repeated further upon user request. The pulses are further used to calibrate the EP recorder 70. In this regard, each pulse within the sequence has the same amplitude. Knowing this, the gain for each channel on the EP recorder 70 may be set by the user so that each channel display has the same amplitude.

With respect to the EP monitoring system, visual conformation may be necessary to validate the EP monitoring system configuration settings since these affect the amplitude of the displayed signal and the invocation of specific noise filter settings and notch filters and are only visual on the EP recorder. A computer prompt could be used initially to prompt confirmation of equal settings (amplitude and filter settings) for each catheter electrode channel. Prompts could also display the common settings and could be user adjustable (via a configuration file) to allow for different manufacturers of EP monitoring systems and variation in setup and configuration.

At step S14, if proper EP monitoring system connection is confirmed by the user the set-up algorithm proceeds to step S16 where it generates a message that the system is ready

only visual on the EP recorder.. A computer prompt could be used initially to prompt confirmation of equal settings (amplitude and filter settings) for each catheter electrode channel. Prompts could also display the common settings and could be user adjustable (via a configuration file) to allow for different manufacturers of EP monitoring systems and variation in setup and configuration.

In one embodiment, the set-up validation and troubleshooting system is implemented in software that is stored in ROM of the processor/controller 34. In alternate embodiments, the software may be stored, transported, and/or utilized while residing on any computer-readable medium for use by or in connection with any suitable computer-based system. In the context of this document, a computer readable medium is an electronic, magnetic, optical or other physical device or means that can contain or store a computer program for use by or in connection with a computer-based system.

The system and method thus described may be easily adapted for use in other ablation systems and is in no way limited to cardiac RF ablation systems. The system and method may find adaptation in any ablation system in which power control systems and various external systems and equipment must interface with each other and with the patient. Other examples of ablation energy sources for power control systems are ultrasound, laser, microwave and cyrogenic energy, each of which results in the ablation of biological tissue.

It will be apparent from the foregoing that while particular forms of the invention have been illustrated and described, various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

AMENDMENTS TO THE CLAIMS

Presented below is a complete set of claims with current status indicators.

1. – 34. (canceled)

35. (previously presented) An ablation system comprising:

a power control system having a multiple pin electrophysiological (EP) monitoring system receptacle having a first pin and a last pin, the power control system adapted to output power signals;

an EP monitoring system adapted to connect to the EP-monitoring-system receptacle, the EP monitoring system including an EP recorder having a plurality of inputs and a display for displaying ECG signals; and

a processor programmed to verify connection between the power control system and the EP monitoring system by outputting a signal to each of the EP-monitoring-system receptacle pins in sequence and displaying the pulses on the EP monitoring system display as a progressive sequence starting with the first pin and ending with the last pin

wherein the processor is further programmed to prevent the output of power signals in the absence of the verification of the connection between the power control system and the EP monitoring system.

36. – 37. (canceled)